UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,479	06/26/2002	Martine Anne Cecile Wettendorff	B45198	4698

20462 7590 09/24/2003

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER
SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/070,479	Wettendorff Martine
Examiner	**Art Unit**
A. R. SALMI	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 8, 2002*

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *21-70* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *21-70* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648.

Response to Amendment

The receipt of preliminary amendment of 3/8/2002, is acknowledged. Claims 1-20 have been canceled. Claims 21-70 have been added and are present.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 21-26, drawn to a vaccine composition of HSV and HPV and adjuvant.

Group II, claim(s) 21, 27, 28, 30, 32, drawn to vaccine composition of HSV and HPV and adjuvant and gp 350 .

Group III, claim(s) 21, 29, 31, drawn to vaccine composition of HSV and HPV and adjuvant and hepatitis A antigen.

Group IV, claim(s) 21, 33, 36, drawn to vaccine composition of HSV and HPV and adjuvant and hepatitis B antigen.

Group V, claim(s) 21, 27, 28, 34, 37, drawn to vaccine composition of HSV and HPV and adjuvant hepatitis B surface antigen.

Group VI, claim(s) 21, 29, 31, 35, 38, drawn to vaccine composition of HSV and HPV and adjuvant and hepatitis B antigen.

Group VII, claim(s) 21, 39, drawn to vaccine composition of HSV and HPV and aluminum hydroxide.

Group VIII, claim(s) 21, 40, 44, drawn to vaccine composition of HSV and HPV and adjuvant and VZV.

Group IX, claim(s) 21, 27, 28, 41, 45, drawn to vaccine composition of HSV and HPV and adjuvant and gpI.

Group X, claim(s) 21, 29, 42, 46, drawn to vaccine composition of HSV and HPV and adjuvant and VZV .

Group XI, claim(s) 21, 33, 43, 47, drawn to vaccine composition of HSV and HPV and adjuvant and gpI.

Group XII, claim(s) 21, 48, 53, drawn to vaccine composition of HSV and HPV and adjuvant and HCMV.

Group XIII, claim(s) 21, 27, 49, 54, drawn to vaccine composition of HSV and HPV and adjuvant and hepatitis and HCMV.

Group XIV, claim(s) 21, 29, 50, 55, drawn to vaccine composition of HSV and HPV and adjuvant and hepatitis A and gB685.

Group XV, claim(s) 21, 33, 51, 56, drawn to vaccine composition of HSV and HPV and adjuvant, and hepatitis B and HCMV.

Group XVI, claim(s) 21, 40, 52, 57, 64, drawn to vaccine composition of HSV and HPV and adjuvant, and VZV and HCMV and SAG1.

Group XV, claim(s) 21, 58, drawn to vaccine composition of HSV and HPV and adjuvant, and Toxoplasma gondii antigen.

Group XVI, claim(s) 21, 27, 59, 65, drawn to vaccine composition of HSV and HPV and adjuvant, and hepatitis and Toxoplasma gondii antigen.

Group XVII, claim(s) 21, 29, 60, 66, drawn to vaccine composition of HSV and HPV and adjuvant and hepatitis A and SAG1 .

Group XVIII, claim(s) 21, 33, 61, 67, drawn to vaccine composition of HSV and HPV and adjuvant, and hepatitis B and TG34.

Group XIX, claim(s) 21, 40, 62, 68, drawn to vaccine composition of HSV and HPV and adjuvant, and VZV and TG34.

Group XX, claim(s) 21, 48, 63, 69, drawn to vaccine composition of HSV and HPV and adjuvant, and HCMV, and TG34.

Group XXI, claim(s) 21, 70, drawn to vaccine composition of HSV and HPV and adjuvant, and multiple variations of formulation of antigens and/or bacteria. (**Please note if this**

group is selected further select one specie to be examined on the merits, see below for explanation)

The inventions listed as Groups I-XXI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group I is known in the prior art as evidence by Lowy et al (U.S Patent NO. 5,855,891) wherein the reference teaches composition of papillomavirus and herpesvirus (see column 7, lines 56-64, and column 8, lines 1-13). The cited evidence prove that the technical feature of Group I does not make a contribution over the prior art. Thus, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

HbsAg S antigen; EBV gp350; VZV gpI; HAV HM-175 inactivated strain; gB685**; pp65; SAG1; TG34.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species confers different structure and presumably different effect on antigenicity .

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

9/19/2003